

## 510(k) Summary

APR - 9 1996

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510(k) Summary Date: November 9, 1995

Device Names: 0.014" Floppy Guide Wire with  
Phosphorylcholine Polymer (PCP) Coating and  
0.014" Intermediate Guide Wire with Phosphorylcholine  
Polymer (PCP) Coating

Classification Name: Catheter Guide Wire (21 CFR 870.1330)

Predicate Device: Advanced Cardiovascular Systems, Inc. 0.014" Hi-Torque  
Floppy II® Guide Wire and 0.014" Hi-Torque Intermediate®  
Guide Wire

### Device Description:

The Floppy and Intermediate guide wires have a nominal outside diameter of 0.014 inch. The guide wires are 175 cm long (nominal) and have a 30 cm radiopaque spring coil joined distally to a central stainless steel core wire. The core wire and spring coils are coated with a hydrophilic phosphorylcholine polymer.

### Intended Use:

The Floppy and Intermediate guide wires are intended for use to facilitate the placement of PTA and/or PTCA balloon dilatation catheters within the peripheral or coronary vasculature. The guide wires are a 0.014 inch size and designed for safe use with appropriately sized balloon catheters. The guide wires are not intended for use in the cerebral vasculature.

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